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STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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Director

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Administrator

DRUG USE REVIEW (DUR) BOARD

Legislative Counsel Bureau
401 South Carson Street
Room 2135
Carson City, NV 89701

Meeting Minutes
March 30, 2006

Committee Members Present:
David England, Pharm.D., Chairman
Keith Macdonald, R.Ph.
Steven Rubin, M.D.
Amy Schwartz, Pharm.D. (called in)
Steven Parker, M.D. (called in)
Marjorie Uhalde, M.D. (called in)

Absent:
Lori Winchell, RNP

Others Present:
Coleen Lawrence DHCFP, Darrell Faircloth AGO, Jeff Monaghan FHSC, Dawn Daly FHSC, Shirley Hunting FHSC, Diana Dills Pfizer, Edward Lewis Pfizer, Terra Robles Pfizer, Bert Jones GSK, Joe Sirna Alpharma, Georgette Dzwilewski, Alan Sloan Purdue, Sandy Sierawski Pfizer, Jim Ball Sankyo, Kirk Huffaker Schering Plough, Tim Crowley Pfizer, Ann Marie Clos Amgen, Roland Baldwin Wyeth, John Plagios, MD, Kele Griffiths Ortho-McNeil, Chris Lepore Johnson & Johnson, Doug Powell Forest Labs, Erick Rouse Eli Lilly.

I. Call to Order and Roll Call

David England, Chairman, called the meeting to order at 1:04 p.m.

II. *Discussion and Approval of December 15, 2005 Minutes

MOTION: **Keith Macdonald motioned to accept the minutes as written.**
SECOND: **Steven Rubin**
VOTES: **Unanimous**
MOTION CARRIED

III. *As Requested by the Pharmacy and Therapeutics Committee, Proposal by First Health Services and Action by Board on Clinical Prior Authorization Criteria for the Following Drugs: [1] The purpose of prior authorization is to encourage appropriate use of these medications. Prior authorization may be appropriate for a number of reasons. Examples include potential toxicity, potential abuse and clinical best practices.

A. Amevive®
B. Enbrel®
C. Humira®
D. Kineret®
E. Remicaide®
F. Raptiva®

Jeff Monaghan stated that after a review of this class by the Pharmacy and Therapeutics Committee (P&T) in January 2006, for the purposes of selecting drugs for the Preferred Drug List (PDL), the P&T Committee felt strongly that clinical criteria for use should be enacted on these drugs and therefore referred this to the DUR Board. These agents are being considered for PA criteria because they are not regarded as first-line agents and all carry a considerable risk of serious side effects up to and including risk of serious infections. Though some of these agents are more likely to be given in an office setting, the P&T Committee is asking they be included in the review because any or all of these agents have been dispensed at the pharmacy level. The DUR Board can consider referral of these criteria to the Division for consideration of PA criteria from a physician office standpoint. What is being addressed today are PA criteria for drugs that will be dispensed at the pharmacy level. He stated that the agents in the proposed criteria (attached) are separated by approved indication and gave a brief overview.

Dave England stated that consideration for approval of these criteria should be based on diagnosis. If a practitioner wanted to use one of these agents for an indication which is not FDA-approved, the onus is on the practitioner to validate to the Clinical Call Center that there is evidence-based literature to support it.

Dr. Parker asked how often the criteria will be revised. He stated that in his discussions with rheumatologists, Enbrel® is approved for the treatment of Juvenile Rheumatoid Arthritis (JRA), but Kinert® is currently being studied and may soon be approved for use in JRA. In addition, new drugs which may be released taking precedence over existing drugs will outdate the criteria. Re-reviews may need to occur in 6-12 month intervals.

Mr. England stated that DUR guidelines are based on the information currently available. As medications are released or discontinued, therapies and evidence-based practices change, the guidelines will need to be reviewed and amended. He stated that criteria will be reviewed yearly and

during the interim until revisions are made, the prescriber can follow the prior authorization process.

Mr. Monaghan stated that this situation also occurs with the Preferred Drug List (PDL). If a new product is released after review of that drug class has occurred, and it's felt that the product cannot wait for the annual review process, the P&T chairman has the ability to add the drug to the PDL on an interim basis until the committee meets to act upon it.

Dr. Parker asked if the prescriber will have to provide justification each time it's ordered and how will it be determined if it's appropriate or not.

Mr. Monaghan stated that the Clinical Call Center will contact him and discuss the situation and he in turn will contact the State to determine if a one time exception should be granted until the criteria is updated and presented to this committee. In addition, there is a formal appeals process in place. When a request is denied, a notice of the decision is sent to the recipient and prescriber and informs them of their appeal rights.

Dr. Parker asked if an indication changes for a drug, how difficult is it for the physician to get that drug if it's outside of the outdated criteria at that point. Ms. Lawrence responded that the Committee could establish policy stating that the agents in this class can be approved for children or adolescents if there is an approved indication without specifically stating the drug names. If a new drug is then released for children or adolescents, it would be covered by the criteria. As for the process, she stated that First Health is obligated under Federal regulation to respond within 24 hours to the request. The Clinical Call Center can do overrides based on the information given by the prescriber and established criteria. If denied, the recipient and prescriber have the right to go through the appeal process.

Public Comment
None

MOTION: Amy Schwartz motioned to accept the clinical prior authorization criteria for injectable immunomodulator drugs as presented.
SECOND: Steven Parker
VOTES: Unanimous
MOTION CARRIED

IV. * Proposal by First Health Services and Action by Board on Clinical Prior Authorization Criteria for Exubera®[1]. The purpose of prior authorization is to encourage appropriate use of these medications. Prior authorization may be appropriate for a number of reasons. Examples include potential toxicity, potential abuse and clinical best practices.

Jeff Monaghan stated that Exubera® is the first inhaled short-acting insulin preparation approved by the FDA. It was approved in January, 2006, and is

anticipated to be released for distribution in June, 2006. He referred the Board to the FDA-approved package insert and the patient medication use guidelines included in the meeting materials. Exubera® is indicated for the treatment of adult patients with Diabetes Mellitus for the control of hyperglycemia. In patients with Type I Diabetes, Exubera® should used be in regimens that contain longer acting insulin. In patients with Type II Diabetes, it can be used as mono-therapy or in combination with oral agents or longer acting insulins. It is not approved for pediatric use (18 years and younger). Clinical studies show that in Type I diabetics, glycemic control appears to be similar to subcutaneous therapy. In Type II Diabetes, inhaled insulin treated patients exhibited greater improvement in glycemic control when compared to oral therapy, however, it was comparable to subcutaneous therapy and there was a higher rate of hypoglycemic events. There are significant precautions with this drug. In clinical trials up to two years duration, patients treated with Exubera® demonstrated greater decline in pulmonary function specifically, FEV_1, and also carbon monoxide diffusing capacity when compared to injectable insulin treated patients. The mean treatment group difference in pulmonary function favoring the comparator group was noted within the first several weeks of treatment and did not change over the two year treatment period. The contraindications are contained within the proposed criteria (attached) and include current smokers, patients who have discontinued smoking within the last six months, and patients with underlying lung disease such as asthma or COPD. The product literature recommends documented pulmonary function tests be performed prior to the initiation of therapy.

Mr. Macdonald stated that the percentages of smokers as well as congestive heart failure and COPD in the Medicaid population are much higher than the general population. This product may be inappropriate for a larger number of people in Medicaid compared to the general population.

Mr. England asked that since there are many varied dosing regimens for insulin, how can Type I and Type II diabetes be controlled with a 1mg and 3mg oral inhaled capsule.

Mr. Monaghan stated that there are conversion charts available and felt that based on safety and clinical experience, a cautious approach should be taken. He met with Dr. Lardinois, Professor of Medicine and Director of Endocrinology at the University Of Nevada School Of Medicine, who also felt a conservative approach should be taken.

Public Comment

Diana Dills, M.D., Pfizer, spoke in support of Exubera® and presented a handout for the Board's review. She stated that Exubera®, rapid acting insulin, is a little faster acting than lispro insulin. The duration of action is half way between that of insulin lispro and regular insulin. In pre-clinical trials, Exubera® was identical to subcutaneous regular insulin in lowering hemoglobin A_{1C}. In superiority trials, Exubera® was superior to the TZD's lowering the hemoglobin A_{1C} to 7.2% versus 8%. She felt the most important use of Exubera® will be in patients who fail two oral agents (sensitizer and secretagogue). When Exubera® was added, lowering

of the hemoglobin A_{1C} was 7.9%. The most effective use was leaving the sensitizer and the secretagogue in place and adding Exubera®. The hemoglobin A_{1C} dropped 1.9%. In all of the studies, Exubera® was effective in reaching the hemoglobin A_{1C} goal that the ADA set of 7%.

Mr. England asked what would be the ideal patient this for use of this medication. Dr. Dills replied the patient that is failing two oral agents and reluctant to use insulin. Mr. England asked with all the insulin dosing levels; e.g., sliding scales, insulin drips, etc., how is the patient's glucose level regulated with a 1mg or 3mg inhaled capsule. Dr. Dill's referred him to the dosing guide contained in the handout and stated that the doses in the guide are based on doses used in the studies. The average dose of insulin in all of the studies with the exception of one was 15-17mg per day and each milligram is roughly 2.8 units. Most patients will use 3, 6 or 9 units before each meal. This gives a starting dose which can be titrated based on the blood sugar.

Dr. Marjorie Uhalde joined the meeting at 1:44 p.m. (call-in).

Dr. Parker asked if the conversion ratio from milligrams to units is consistent from patient to patient or does it vary. Dr. Dills replied that it's consistent (1mg per 2.8units) with the exception of smokers which is why they are eliminated from this practice.

Mr. England asked what the cause is for decreased lung function with use of inhaled insulin. Dr. Dills stated that she did not know what the cause is but Type I patients lose about 1% of lung function and whatever causes this occurs rapidly within two weeks of starting Exubera®. The lung function then declines in parallel to the comparators. As we age, we lose 20-30mls per year. Patients with Type I Diabetes lose about 30mls per year. When Exubera® was discontinued, the lung function returned to where the non-comparator was which was not normal because everyone had declined. Patients with Type II diabetes lose lung function about 58mls per year. When started on Exubera®, Type II's lost approximately 1%. They paralleled to comparators and when Exubera® was discontinued, it went back up to where the normal aging process would be.

Mr. England asked what her recommendation for criteria would be. Dr. Dills replied non-smoking and, according to package insert, treat people with normal lungs. She stated that they have ongoing studies looking at asthma and COPD and felt pulmonary functions tests should be done since there is no data stating that it's safe for this group.

Mr. England stated that the proposed criteria presented by First Health meets the guidelines as proposed by the manufacturer. After the medication is released and there are more clinical and more public use of the medication outside of a clinical situation, the committee would be remiss to not go back and re-review the criteria because there will be changes post-marketing of the medication.

Dr. Rubin agreed there should be re-review in three, six or twelve months when there is data from actual clinical experiences.

Amy Schwartz asked if Symilin® has been addressed by this committee and Mr. England replied no. She said that Symilin® is currently available on the market and indicated and yet consideration is being given to a medication that is not on the market.

Mr. England suggested that this committee may want to consider reviewing all the anti-diabetic agents at the next meeting.

Ms. Lawrence said that although the drug is not available at this time, it takes a minimum of ninety days to get a new policy through the public hearing process. She reminded the committee that this discussion is to determine clinical criteria for this drug and does not impact the Preferred Drug List.

Dr. Parker questioned adding it to the formulary if it has not yet been released. Since the drug has not been approved to be released, we could say at this point in time prior to knowing what the official instructions for use will be, these don't sound like bad guidelines, but they may need to be changed when the drug is released because it may come out with different recommendations. Are these FDA approved guidelines?

Mr. Monaghan responded that this drug class is not governed by the Preferred Drug List (PDL). You're not technically adding a drug to a formulary but recommending clinical criteria for use which is the role of this committee. If clinical criteria are not established, once the drug is released, it will be available with no restrictions for use. The package insert and patient medication use criteria have been approved by the FDA.

Dr. Parker asked if the criteria are FDA approved. Mr. Monaghan responded that the issues are addressed. Included from a safety and effectiveness standpoint is the recommendation that people be not able to use subcutaneous insulin before they go to this product. Most Type I diabetics have to take a short-acting injectable insulin. In this case, there probably won't be that many Type I diabetics that would qualify for this unless they were unable to either self-administer the insulin injection or have a care give available that could inject insulin.

Dr. Rubin stated that criteria as it stands are based on controlled studies with controlled information, controlled release, and he felt hesitant to take any action until there was actual clinical experience with risk and benefits. He felt it would be prudent to be prepared to adjust the criteria closer to the time of taking action and approving it for use and did not support approving criteria in anticipation because criteria may need to be changed.

Mr. Monaghan responded concrete contraindications are known now and if no action is taken now, it will be three to six months after release of the drug before criteria can be in place. He stated that this is an FDA-approved product with an FDA-approved package insert.

Dr. Parker asked for clarification that the FDA-approved indications exist and have been incorporated in to the proposed criteria presented today. In addition, two more restrictions have been added: 1) the Type I diabetic cannot self-inject and 2) the Type II diabetic is unresponsive to oral therapy. Mr. Monaghan stated that is correct.

Dr. Parker asked if the request is to have guidelines in place in the event the P&T Committee approves this drug for the PDL. Ms. Lawrence stated that the anti-diabetic medications are one of six drug categories excluded from PDL review per NRS 422. Therefore, this drug will not be reviewed by the P&T Committee but can be reviewed by the DUR Board to establish criteria for use.

Mr. Monaghan stated that establishing limitations beyond the package insert is not unique to this drug. PA criteria are based on best clinical practices and clinical judgment as opposed as to what's in the insert.

MOTION: **Keith Macdonald motioned to accept the criteria as presented with the circumstance to re-review when more clinical data is available.**
SECOND: **Amy Schwartz**
Dr. Parker made a friendly amendment that the criteria be re-reviewed six months after release of the product. Mr. Macdonald accepted the friendly amendment and Ms. Schwartz seconded.
AYES: **Dave England, Keith Macdonald, Amy Schwartz, Steven Parker, Marjorie Uhalde**
NAYES: **Steven Rubin**
MOTION CARRIED

V. *Proposal by First Health Services and Action by Board to Apply/Revise Quantity Limitation Edits on the Following:

A. Relpax® Tablets (Creation of New Quantity Edit)

Jeff Monaghan stated that there are currently quantity limitations on the triptans. Eletriptan (Relpax®) was not included on the initial list and recommended it be included (12 tablets per month for the 20mg and 40mg tablet).

Dave England asked if the same criteria were applied in determining the quantity as with the other triptans and Mr. Monaghan replied yes.

Public Comment
None

MOTION: **Amy Schwartz motioned to accept the quantity limitations on Relpax® as presented.**
SECOND: **Steven Parker**
VOTES: **Unanimous**
MOTION CARRIED

VI. Presentation by First Health Services and Discussion by Board of Prospective Drug Utilization Review (ProDUR) Reports

A. Top 50 Drugs Ranked by Payment Amount
B. Top 10 Therapeutic Classes by Payment Amount
C. ProDUR Message Report

Jeff Monaghan presented Drug Utilization Reports (attached). He referred to the top fifty drug report for calendar year 2005, and stated that with the enactment of Medicare Part D, there will be a shift in utilization in future reports. Preliminarily what has been noted are a relative decrease in narcotic usage and an increase in some of the medications used for children; e.g., Synagis. Many of the chronic medications have moved to Part D. The drug classes that continue to show an increase in volume and expenditure are those in the antipsychotic category.

VII. Presentation by First Health Services of Retrospective Drug Utilization Review Results

Jeff Monaghan presented RetroDUR reports (attached).

Dr. Parker excused himself from the meeting at 2:19 p.m.

VIII. Report by First Health Services on Planned Educational Initiatives

Jeff Monaghan stated that at the last meeting, there was discussion regarding collaborating with the Nevada College of Pharmacy on educational development. He has discussed this with Amy Schwartz who is responsible for the post-graduate education efforts at the college of pharmacy and has offered to facilitate for the college.

Ms. Schwartz stated that the key area of that discussion was education for pharmacists, physicians and other providers within the state regarding medication therapy management. She felt that there are also opportunities for providing patient education seminars. There have been past discussions by this committee regarding educational programs in the area of antipsychotics or medication use in psychiatry in general. She stated that the college would be happy to assist with these types of educational efforts.

Dave England stated that some of the past programs have been coordinated through the University of Nevada School of Medicine. He said that he would like to see a joint effort by the College of Pharmacy and the School of Medicine in order that all practitioner types can participate. He felt that the information is prevalent and important to pharmacist, physicians, nurses, nurse practitioners, etc. He stated that this is a healthcare issue not just a pharmacist or physician or nursing issue.

Ms. Schwartz stated that she does view this as an interdisciplinary process. If there is unique importance specific to one of the healthcare disciplines, then those

types of individual programs can also be offered. Currently, the College of Pharmacy is only pursuing pharmacist CE accreditation and it would be good to partner with someone who has medical CME accreditation.

Coleen Lawrence recommended pursing narcotics and antipsychotics as the educational front for the next year. Dr. Rubin requested psychotropics as opposed to antipsychotics. Mr. England agreed and stated that he would like to see the following topics pursued and ranked as 1) psychotropics, 2) biologicals, and immunomodulators, and 3) narcotics. He said a pain management program was offered within the past five years and Mr. Monaghan added that a program on opioid equivalency was conducted last year.

Mr. England requested a tentative outline be presented at the next meeting.

IX. Old Business

A. Presentation by DHCFP on the status of the Medicare Modernization Act

Ms. Lawrence stated that the Medicare Modernization Act (MMA) was enacted on January 1, 2006. Approximately 16,000 fee-for-service Medicaid recipients became eligible for Part D. The State of Nevada has opted to pay the co-payments for those recipients that are dual eligible (eligible for Medicare Part D and Medicaid). Though Medicaid is processing the co-pays through the Point of Sale system, the co-pays are funded through other State funds. Co-pay for dual eligibles are $1 (for generics) and $3 (for brand name drugs). Once the co-pay functionality was in place, it was discovered that there are 400-600 low income subsidy dual-eligibles whose co-pays are appropriately $2 and $5. Because the co-pay functionality was not in place until 2/21/06, some recipients may have erroneously been required by the pharmacy to pay the co-pay. The State is working on communication to the pharmacies clarifying the co-pay amounts and requesting that pharmacies resubmit to Medicaid co-pay claims which were paid by recipients and in turn refund the recipients. Funds received by the State from CMS for MMA education and outreach will be used to run radio spots informing recipients to work with their pharmacy on co-pay refunds and the State is also working with the Retail Association of Nevada on distributing informational flyers to recipients within the pharmacies .

Ms. Lawrence said that diabetic supplies are a covered benefit under Medicare Part B and not covered under Medicare Part D. For eligible recipients, Medicaid covers the 20% Part B co-pay for these supplies. She stated that DHCFP and First Health are working on a communication informing pharmacies on the process for Medicaid reimbursement of the Part B co-pay.

Public Comment

No comment.

X. *Adjournment

The next meeting is scheduled for June 22, 2006, in Northern Nevada.

MOTION: **Amy Schwartz motioned for adjournment.**
SECOND: **Steven Rubin**
VOTES: **Unanimous**
MOTION CARRIED

Meeting adjourned at 2:44 p.m.